2/12/99

SCI-PHARM ®

...chemistry working for medicine and dentistry...

SCIENTIFIC PHARMACEUTICALS, INC.
3221 Producer Way • Pomona, California USA 91768
PHONE: (909) 595-9922 • Outside California (800) 634-3047 • FAX: (909) 595-0331
E-MAIL: scipharm@msn.com • WEBSITE: http://www.scipharm.com

K982915

510(k) SUMMARY

(1) Submitted by: Dr. Jan A. Orlowski
Scientific Pharmaceuticals, Inc.
3221 Producer Way
Pomona, California 91768
phone: 909-595-9922

Date Prepared: August 18, 1998

(2) Device Trade Name: Sci-Pharm *DFV* Varnish
Device Common Name: Dental Varnish
Device Classification Name: Cavity Varnish

(3) Sci-Pharm *DFV* Varnish is substantially equivalent to Duraphat by Colgate-Palmolive and Durafluor by PharmaScience (as shown in the table in Point 4 below).

(4) *Chemical Composition*

Ingredient	Sci-Pharm *DFV* Varnish	Colgate *Duraphat*
Ethyl Alcohol	71.25%	75%
Colophony	20%	20%
Sodium Fluoride	5%	5%
Water	3.75%	<1%

Device Function

The varnish has the consistency of a viscous liquid. When applied in a thin layer over tooth dentin, the solvent (ethyl alcohol and water) evaporates within a few minutes, leaving a film of Colophony resin in which Sodium Fluoride is suspended, which adheres well to the tooth structure.

(5) The use of varnishes similar or virtually identical to Sci-Pharm *DFV* Varnish is accepted worldwide for three major functions:
- temporary reduction of sensitivity of teeth where dentin or cementum is exposed
- reduction of post-operative sensitivity
- caries prevention under restoratives and cements

(6) The technological characteristics (i.e., chemical composition and device function) of Sci-Pharm *DFV* Varnish are similar to that of cavity varnishes which have been in widespread use for many decades. It is virtually identical to varnishes currently commercially available (Duraphat by Colgate-Palmolive and Durafluor by PharmaScience), the only difference being that it incorporates an azeotrope of ethyl alcohol and water (95:5 ratio) as solvent instead of pure ethyl alcohol, in order to achieve faster cure and reduced potential of initial irritation of very sensitive teeth.

(7) In order to determine substantial equivalence of Sci-Pharm DFV Varnish to Duraphat and Durafluor, the identity and concentration of solvents (carriers), resin, and fluoride salt comprising Duraphat and Durafluor versus those comprising Sci-Pharm *DFV* Varnish were determined and confirmed by tests including: IR spectrophotometry, pyrolysis, viscosity and refractive index measurements, and dry residue determination.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 1999

Dr. Jan A. Orlowski
Scientific Pharmaceuticals, Incorporated
3221 Producer Way
Pomona, California 91768

Re: K982915
Trade Name: Sci-Pharm DFV Varnish
Regulatory Class: II
Product Code: LBH
Dated: November 25, 1998
Received: December 1, 1998

Dear Dr. Orlowski

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K982915

DEVICE NAME: SCI-PHARM DFV VARNISH

INDICATIONS FOR USE:

For use as a varnish on sensitive teeth over exposed dentin and under temporary restoratives and cements where post-operative sensitivity is of concern.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

*None of the above: FOR PROFESSIONAL USE ONLY

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K982915